ADAP ADVISORY COMMITTEE MEETING October 11, 2006 Henrico Doctors Hospital

Members Present: Gregory Townsend, MD, Robert Brennan, MD, Bob Higginson, PA, Craig Parrish, RPh, Linda Eastham, RN, FNP, Daniel Nixon, DO, and Donald Walker.

VDH Staff: Diana Jordan, RN, MS, Steve Bailey, LCSW, and Faye Bates, RN

Other: Anne Rhodes

The meeting was called to order at 10:05 a.m. by Diana Jordan, Director of Health Care Services. She announced that Dr. Miller will be retiring at the end of the month, and she has been appointed as chair of the committee. The minutes of the previous meeting were read and approved with no amendments.

Diana Jordan provided an update on Ryan White reauthorization. The House passed bill HR 6143, but it did not get through the Senate prior to adjourning the session. Congress will reconvene on November 13, 2006. Reauthorization in its current language would likely increase funds to Virginia. If reauthorization does not occur, Virginia may lose ADAP supplemental funds, which would be used to "hold harmless" states that would see significant cuts due to lack of a mature HIV name-based surveillance system. Virginia would expect to see a small increase in Title II base funds that may offset some of the ADAP loss. If reauthorization occurs, it is uncertain when it would actually go into effect. Appropriation of funds is still pending and will have to be acted upon when Congress reconvenes. VDH will update Committee members as these issues are resolved.

VDH will seek to add local health department representation to the ADAP Advisory Committee, consisting of a health director and a local ADAP Coordinator.

Diana Jordan reviewed the ADAP Medicare Part D Policy for clarification. Medicare-eligible ADAP clients enrolled in a Part D plan must apply for low-income subsidy (LIS) if their income is less than 150% federal poverty level (FPL). Clients who qualify for the full LIS will need to utilize their Medicare Part D Plan for their medications. Clients who qualify for a partial LIS, usually with incomes 135% to 150% FPL, and are unable to afford or obtain assistance with Part D cost sharing may request an ADAP eligibility exception through the local health department. If a client is not eligible for LIS, the client can continue on ADAP. At HRSA's direction, if a client refuses to enroll in a Part D plan but does not have other access to medications, the client may still utilize ADAP.

There will be a change in the mechanism to distribute ADAP program and policy updates. Previously, a revised ADAP Memorandum was distributed to communicate changes, but an increasingly complex formulary has contributed to a cumbersome document. Faye Bates is developing documents that will be posted on the VDH website, and committee members will be notified when this is completed.

The Medical Monitoring Project (MMP) is still in the process of recruiting sampled providers.

The Incidence and Resistance Surveillance data is not yet cleared for release. Information on this project will be provided at the next Advisory Committee if possible.

Anne Rhodes, Data Manager for Virginia Commonwealth University Survey and Evaluation Research Laboratory, presented the ADAP data report. The average monthly cost per person on ADAP is \$1259. The average length of time a person is on ADAP is 48 months. The growth rate for the first 8 months of 2006 is -1.3%, compared to .5% in 2005, with 2669 clients currently active. This may be due in part to enrollment in Medicare Part D, as many clients who no longer access ADAP were below 135% FPL. Despite a slight decrease in the number of active clients on ADAP, there has been a steady rise in cost per client. Faye Bates will be monitoring medication cost trends, new client enrollment, and laboratory results on a quarterly basis. This information will be compared to previous ADAP medication utilization and cost over the past 5 years. Demographic trends revealed an increase in the female and Hispanic populations as new enrollees. As of June 2006, 58.3% of ADAP clients were between the ages of 20 to 44. Drug utilization trends showed PI boosting with ritonavir has increased over the last 3 years.

Faye Bates presented follow up information from the 2005 Seamless Transition report as requested from the June ADAP Advisory Committee meeting. In 2005, there were a total of 89 referrals to the program. There were 51 inmates that failed to make their initial appointments. Three of these inmates enrolled in ADAP several months after the initial referral. All 3 presented to a different health department than originally referred. There were 8 inmates that presented to local health departments in 2006 as new clients. Committee discussion identified possible contributing factors to appointment failures may be due to lack of education, failure of discharge planning, issues of disclosure, and confidentiality concerns. It was also mentioned that basic needs such as food, shelter, and employment often take priority over health care. Acknowledging difficulties in reaching clients that did not enter care, Committee members suggested surveying clients that kept appointments, to identify motivations and barriers associated with the program. The use of incentives was mentioned to foster compliance. At present, there are programs in the Eastern and Central regions attempting to address needs of the post released prisoner population. Faye Bates will compile a listing of these programs.

Faye Bates presented a description of adherence tools and strategies used by local health departments. Adherence strategies included letters to clients as reminders to update annual eligibility, letters to providers requesting laboratory information and prescriptions, and provider notification of client noncompliance with picking up medications or completing ADAP eligibility. Some of these adherence tools will be posted on the VDH website. A self assessment tool from one of the local health departments was shared which generated interest. A copy of this tool will be sent to committee members.

Steve Bailey presented on the upcoming State Pharmaceutical Assistance Program (SPAP). This is the first SPAP in the U.S. that is HIV specific. Virginia's General Assembly approved a budget amendment to VDH for \$300,000 per year for this budget cycle for this program. The goal is to provide financial assistance to wrap around coverage for ADAP clients enrolled in a Medicare Part D program to assist clients in reaching catastrophic coverage. ADAP resources will be conserved by assisting clients to obtain medications through their Medicare Part D benefit. The program will be implemented in two phases. Phase one will consist of VDH providing funds for premium payments to clients. Phase two will include full implementation of the program, including provision of funds for copays/coinsurance, deductibles and full medication costs during coverage gaps. A Request for Proposal will be issued for a provider to coordinate the full implementation of this program.

Dr. Robert Brennan gave a clinical update from the Ryan White All Grantees Meeting, which included a presentation on Hepatitis B (HBV) disease. Presentations of the Ryan White All Grantees Meeting are available through the Health Resources and Services (HRSA) website at http://www.rwca2006.com/agenda.asp.

Dan Nixon presented additional information about Hepatitis B infection, discussing issues related to disease manifestation, progression and treatment resistance.

Discussion was facilitated to determine whether treatments for HBV should be considered for addition to the ADAP formulary. Several points were made by Committee members. It was acknowledged that there is no clearly documented prevalence data of HBV in various HIV treatment settings, but estimates range from less than 5% to about 10%, with a smaller percentage medically eligible for treatment. Efficacy data for existing FDA-approved treatments is still relatively short-term. Treatment is likely ongoing, as the treatment goal is suppression not eradication. Among various options discussed, entecavir appeared to be more likely to be utilized than other options, with a cost-estimate of about \$485 per month per client (under VDH pharmacy pricing), resulting in about \$50,000 annual cost to ADAP based on rough patient prevalence estimates. It was acknowledged that other factors that may need to be considered would include criteria for treatment, role of hepatology in treatment, and longer term efficacy data. Steve Bailey will investigate the availability of treatments through pharmaceutical assistance programs. The decision of whether to move forward with pursuing addition of HBV treatment options to ADAP at this time will be carefully considered with this discussion as a basis.

Faye Bates presented information on the newly approved vaccine for Human Papillomavirus (HPV). According to the FDA, this vaccine offers protection against HPV types 6, 11, 16, and 18 which cause 70% of cervical cancer and 90% of genital warts. The vaccine is indicated for females 9 to 26 years of age. There was discussion on the pros and cons of vaccine usage in HIV-infected females. There is insufficient scientific data available at this time for consideration as a formulary addition. This issue will be revisited at a later date when more data is available for use in the HIV-infected population.

Meeting was adjourned at 2:00 p.m. Next meeting is planned for February 2007, with date and place to be determined.